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ALKYL DIPHENYL OXIDE SULFONATES

(ADPODS)

HPV CHALLENGE PROGRAM

CATEGORY, TEST PLAN AND ROBUST SUMMARIES

OF DATA FOR HPV/SIDS ENDPOINTS

Submitted to the U.S. Environmental Protection Agency

Under the High Production Volume (HPV) Chemicals Challenge Program

By

The Dow Chemical Company, Midland, Michigan, 48674

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I. Introduction

The alkyl diphenyl oxide disulfonates (ADPODS) is a large class of chemicals that have been produced by The Dow Chemical Company and others and used in commerce for decades. This document describes in some detail, the chemical and toxicological particulars about seven members of this class.

Commercial Dow ADPODS substances are characterized by the length and structure of the alkyl group and the predominant disulfonation. Commercial ADPODS substances are primarily monoalkylated, primarily disulfonated and available in both the acidic and sodium salt forms. Some dialkylated and monosulfonated substances are present with the intended monoalkylated, disulfonated components and this is reflected in the names assigned to the ADPODS produced by Dow in the US. Other nomenclature is applied to these substances outside the US. In addition to commercial Dow ADPODS substances, Dow submitted PMNs for ADPODS manufacturing intermediates to the final products, which are all referenced in this test plan.

The Dow Chemical Company voluntarily commits to provide hazard information on five ADPODS (alkyl diphenyl oxide sulfonates) chemicals listed as HPV chemicals under The U.S. Environmental Protection Agency (EPA) High Production Volume (HPV) Chemicals Challenge Program. Hazard information on two closely related ADPODS is provided to support the category approach for the ADPODS.

The EPA HPV Challenge program was initiated to develop a screening-level data set for chemicals that are produced or imported into the U.S. in amounts greater than one million pounds/year. This program is similar to the data-collection goals of the Organization for Economic Cooperation and Development (OECD) Screening Information Data Set (SIDS) Program. The HPV data set includes

collection of data on physical-chemical properties, environmental fate, ecological toxicity, mammalian toxicity and genetic toxicity. A provision of the HPV program allows the development of categories of chemicals that are formed based upon structural similarity or on chemicals that share common chemical properties (U.S. EPA, 1999). The development and justification of chemical categories based on structure-activity relationships (SAR) results in a significant reduction in the use of animals for toxicity testing and expedites the production of data to evaluate the chemical category.

The seven ADPODS chemicals summarized in this Test Plan are being submitted as a single category.

II. Use of Category

A. Rationale for ADPODS Category under HPV Challenge Program

The ADPODS category consists of five ADPODS chemicals listed as HPV chemicals. Data for two additional ADPODS chemicals that have recently been subjected to more health and environmental studies have been added in summary to enrich the database on this category. Additionally, data from tests of the dry forms of two of the chemicals (the C6 and C16 members of the group) have also been included in order to more fully complete the data package. (These chemicals are normally sold as aqueous solutions and so have routinely been tested as such.) All of these ADPODS chemicals have a common Structure-Activity-Relationship [SAR] to serve as the technical basis for the category under the EPA HPV Challenge Program.

In the EPA Guidance Document entitled Development of Chemical Categories in the HPV Challenge Program, under Section II entitled Definitions, the following information is given:

"A chemical category, for the purposes of the Challenge Program, is a group of chemicals whose physicochemical and toxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity. These structural similarities may create a predictable pattern in any or all of the following parameters: physicochemical properties, environmental fate and environmental effects, and human health effects. The similarities may be based on the following:

- a common functional group[e.g., aldehyde, epoxide, ester, etc.]; or

- the likelihood of common precursors and/or breakdown products, via physical or biological processes, which result in structurally similar chemicals [e.g., the "family approach" of examining related chemicals such as acid/ester/salt]; and

- an incremental and constant change across the category [e.g., the dimethylene group difference between adjacent members of the alpha-olefins]-"

The EPA Guidance Document subsequently gives three examples of acceptable categories. One of the examples is entitled the Linear Alkyl Benzene Mixtures, consisting of nine different commercial formulations, with each formulation containing various proportions of individual Linear Alkyl Benzenes that all share a common structural basis.

The ADPODS Category proposed herein complies with the EPA definition of an acceptable Category based on all three criteria cited above, namely

[a] the sharing of a common functional group {all sulfonated derivatives of Alkyl Diphenyl Oxide},

[b] the likelihood of common precursors and/or breakdown products via physical or biological processes, which result in structurally similar chemicals (disulfodiphenyloxide carboxylate as the biodegradation product), and

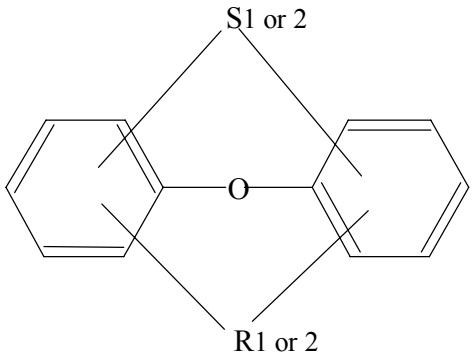
[c] incremental changes in chemical structure as one progresses from C6 linear[1] alkylate to a C16 linear alkylate.

The attached spreadsheet (*Appendix A*) is a tabulation of the HPV/SIDS data compiled for the members of this single category of ADPODS surfactants.

[1] Although the products are referred to as linear and branched, the linear forms are actually secondary alklys. They are made from linear alkylate raw material but chemistry forces attachment at the second carbon. The branched ADPODS are produced from tetrapropylene alkylate.

B. Description of Members

The basic structure of the class of substances is as shown here.



Where,

S1 = monosulfonated, acid or sodium salt (minor component)

S2 = disulfonated, acid or sodium salt (major component)

R1 = monalkylated, 'linear' or branched C6, C10, C12, or C16 (major component)

R2 = dialkylated,'linear' or branched C6, C10, C12, or C16 (minor component)

The Criteria that define this Category entitled ADPODS are as follows:

[a] Each member is based on, and must include the Diphenyl Oxide structure,

[b] Each member has one (primarily) or two alkyl side chains ranging from C6 to C16,

[c] Each member has one or two (primarily) sulfonate group attachments, offered as either the acid or sodium salt, and

[d] Each member has common functionality as a bipolar anionic surfactant.

Thus, the seven members of the proposed category are described in the following table.

CAS # and Description of Chemicals in ADPODS Category

CAS # of ADPODS Member	TSCA Chemical Name	Current Commercial Name(s)	Description of Member	Comments
147732-60-3	Benzene, 1,1'-oxybis-, sec-hexyl derivs., sulfonated, sodium salts	DOWFAX* C6L DOWFAX* HYDROTROPE DOWFAX* DRY HYDROTROPE anionic surfactant (aqueous solution and powder, resp.) (older name XD-8292)	C6 Linear ADPODS, Sodium salt	Not on EPA HPV List, added to further enrich Category via use of recent data
70191-75-2	Benzenesulfonic acid, decyl(sulfophenoxy)-	DOWFAX* 3B0 anionic surfactant	C10 Linear ADPODS, Acid	Listed on EPA HPV List (not HPV for Dow)
36445-71-3	Benzenesulfonic acid, decyl(sulfophenoxy)-, disodium salt	DOWFAX* 3B2 anionic surfactant	C10 Linear ADPODS, Sodium Salt	Listed on EPA HPV List (HPV for Dow)
28519-02-0	Benzenesulfonic acid, dodecyl(sulfophenoxy)-, disodium salt	Outside the US: DOWFAX* 2A1 anionic surfactant	C12 Branched ADPODS, sodium salt	Not produced by Dow in the US. Produced as CASRN 119345-04-9 in the US
149119-20-0	Benzene, 1,1'-oxybis-, sec-dodecyl derivs., sulfonated, sodium salts	XDS-8174.00 anionic surfactant	C12 Linear ADPODS, Sodium Salt	Listed for HPV purposes under CAS 28519-02-0 (not HPV for Dow)
119345-03-8	Benzene, 1,1'-oxybis-, tetrapropylene derivs., sulfonated	DOWFAX* 2A0 anionic surfactant	C12 Branched ADPODS, Acid	Listed on EPA HPV List (not HPV for Dow)
119345-04-9	Benzene, 1,1'-oxybis-, tetrapropylene derivs., sulfonated, sodium salts	DOWFAX* 2A1 anionic surfactant	C12 Branched ADPODS, Sodium Salt	Listed on EPA HPV List (HPV for Dow) Described on EINECS European Inventory CASRN as 28519-02-0 with CASRN 25167-32-2
65143-89-7	Benzenesulfonic acid, hexadecyl(sulfophenoxy)-, disodium salt	DOWFAX* 8390 DOWFAX* Detergent DOWFAX* Dry Detergent anionic (aqueous solution and dry powder, resp.) (older name(s): XD-8390 and XD-8390-D)	C16 Linear ADPODS, Sodium Salt	Not on EPA HPV List, added to further enrich Category via use of recent data

*Trademark of The Dow Chemical Company

C. Precedence for Use of Category Approach to ADPODS Chemicals

There is relevant regulatory precedence for application of a category approach in addressing the toxicity and environmental testing of ADPODS chemicals. In 1992, The Dow Chemical Company submitted a series of PMN's to the U.S. EPA for intermediates to commercial ADPODS final products. The pre-notice communications resulted in the successful, agreed upon use of operational chemical grids accommodating multiple PMN chemicals based on ADPODS chemistry. These discussions resulted in agreement on the creation of an operational grid/box accommodating the 150 plus candidate ADPODS. The grids included the four major components of the ADPODS, namely the MAMS [MonoAlkylated, Mono Sulfonated DPO]; the MADS [MonoAlkylated, Disulfonated DPO]; the DAMS [DiAlkylated, Mono Sulfonated DPO] ; and the DADS [DiAlkylated, DiSulfonated DPO] plus the variants of up to seven Alkyl chain lengths [ranging from C6 to C16+] and several salts derived from the acid forms of the ADPODS chemicals. Agreement was reached between Dow and EPA to conduct basic environmental tests on six representative ADPODS chemicals and one acute mammalian toxicological test on one representative ADPODS chemical chosen from within the operational grid/box. The resultant data were used as representative surrogate data for all of the candidate ADPODS variants within the grid/box [Dow Chemical Company Communication to Miriam Wiggins-Lewis, U.S. EPA, March 3, 1992]. The successful use of this paradigm for the Agency's PMN review for these chemicals is offered as additional support for the validity of the category proposed by Dow.

In the agreement with EPA, a series of tests was conducted on the variants for the C6 and C16 substances within the grids. The tests included trout, daphnia and algae acute toxicity tests for each variant for each C6 or C16 (total of 18 tests in all)--plus one acute mammalian toxicity study. Those tests are not included in this data set. We reference this previous interaction between EPA and The Dow Chemical Company for the purpose of illustrating the acceptability of the ADPODS class/category approach in previous governmental agreements. The following Table lists the C6 and C16 variants which were tested and the CAS numbers used in the EPA PMN. Some of the tests conducted on the 'commercial product' were in reality tests conducted on one or several of the individual non-commercial variants. This is always denoted in the Robust Summaries and in data tables.

CAS # of ADPODS Member	Commercial Name	Description of Member	Comments
169662-17-3	None	MAMS: monoalkylated C6,	Not on EPA HPV List

		monosulfonated, sodium salt	
16989-92-5	None	MADS: monoalkylated C6, disulfonated, disodium salt	Not on EPA HPV List
169662-22-0	None	DADS: dialkylated C6, disulfonated, disodium salt	Not on EPA HPV List
16989-93-6	None	MAMS: monoalkylated C16, monosulfonated, sodium salt	Not on EPA HPV List
65143-89-7	None	MADS: monoalkylated C16, disulfonated, disodium salt	Not on EPA HPV List
70191-76-3	None	DADS: dialkylated C16, disulfonated, disodium salt	Not on EPA HPV List

The Dow products included in this ADPODS category are sold commercially under the name DOWFAX* anionic surfactants. These surfactants are available globally. They are used in a wide range of applications, including (but not limited to) cleaning products, emulsion polymerization, textile dyeing, oil field applications, as inert ingredients in agricultural formulations, electroplating, vapor and mist suppressants, and pulp and paper applications.

These substances are stable across the entire pH range and have excellent thermal stability. They are extremely soluble in aqueous media and not readily soluble in fat.

III. Data and Test Plan

A. Development of Robust Summaries and Study Scoring Criteria

For purposes of this program, the IUCLID (International Uniform Chemical Information Database) format has been used for preparation of robust summaries for the HPV program. Because many of the fields in the IUCLID database program are outside the scope of the HPV program, some of these fields may have been left blank in the IUCLID robust summary. Scoring of studies from company files for reliability to fulfill the testing requirement for each endpoint used a system similar to that published by Klimisch et al. (1997). Studies were given a score of "1" if the data could be considered valid without restriction based on the completeness of the protocol and adequate details in reporting. Studies were given a score of "2" if the data and study design could be considered scientifically valid to address the endpoint but with restrictions due to lack of various technical or reporting details or deviations from current OECD guidelines. Studies were given a score of "3" indicating a lack of validity to address the endpoint by themselves, but this score indicated that the study could

provide supplementary information that could be used to address the endpoint in a weight of evidence evaluation in the absence of other data.

No studies which might have fit a score of "4" were included in IUCLID. They were not considered usable for the purpose of the HPV Challenge program (e.g., company product brochures/summaries, abstracts, review articles, etc.) and so were not used.

B. Description of Data and Test Plan

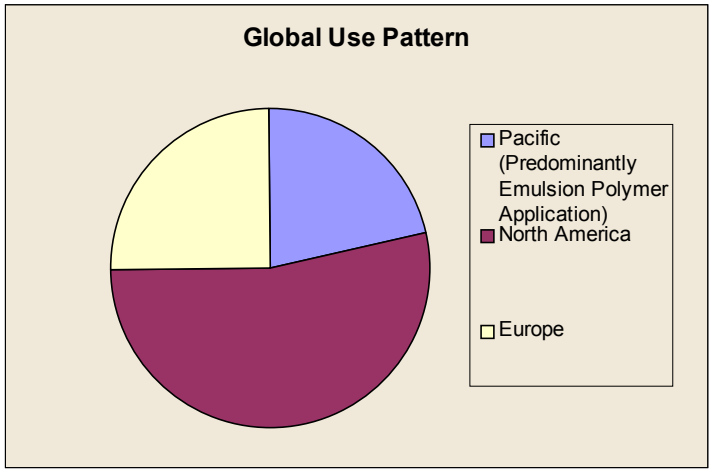
Review of the data currently available on these compounds confirms the validity of this ADPODS category, with similar/predictable activity in regard to physical/chemical properties, environmental fate, environmental effects and human health effects to be addressed in the EPA HPV Testing program.

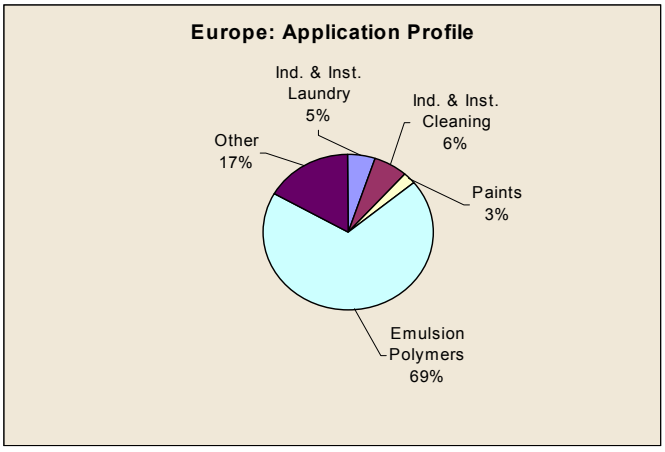
As the boundaries of the Category are defined by the shortest Alkyl chain length [C6] and the longest alkyl chain length [C16], these two boundary representatives can effectively serve as [1] the boundaries for the physical/chemical/biological properties of this ADPODS Category, and [2] the technical basis upon which interpolation/equivalency can be used to represent the ADPODS as a single, unified Category.

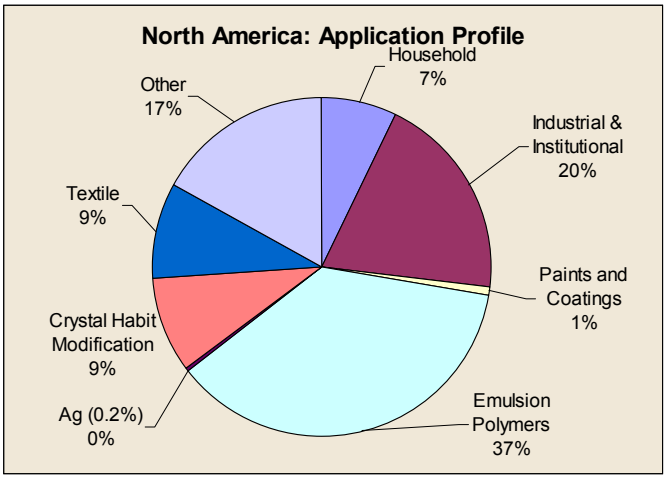
Appendix A summarizes individual hazard data for each member of the category.

Use Pattern (IUCLID 1.7)

Information about applications is available for the category but not specifically for individual members of the category. Thus, IUCLID shows generic use categories. More specific relative use patterns are shown here as pie charts.


Global Use Pattern
Pacific (Predominantly Emulsion Polymer Application)
North America
Europe


Europe: Application Profile
Ind. & Inst. Laundry 5%
Ind. & Inst. Cleaning 6%
Other 17%
Paints 3%
Emulsion Polymers 69%



Emulsion polymerization of latex represents the largest use application for the ADPODS surfactants. This application represents 37% of worldwide use, essentially 100% in Japan and 69% in Europe. Outstanding stabilization is achieved in polymerization by these anionic surfactants. DOWFAX 2A1 is mainly used with styrene-butadiene systems and also in styrene-acrylics and in all acrylic latex. DOWFAX 2A1 complies with the Food Additive regulation 21 CFR 178.3400, for use in indirect food additive applications such as latex for adhesives, for paper coatings and for the manufacture of articles intended for use in the food industry.

Cleaning, specifically Industrial and Institutional cleaning, is the second largest use of DOWFAX surfactants in North America. The high solubility of DOWFAX surfactants is ideal for concentrated aqueous products, which are often shipped in a concentrated form and then diluted for actual use. The disulfonated structure of the DOWFAX surfactants makes them highly soluble in strong acid and alkali solutions. DOWFAX surfactants are not affected by mono- or divalent ions, so they are an excellent choice for hard water applications. DOWFAX surfactants do not promote the degradation of sodium hypochlorite bleach and are often used as fragrance solubilizers in bleach-based formulations. Due to these unique properties, DOWFAX surfactants are found in a wide variety of cleaning applications/products. DOWFAX surfactants are often used as co-surfactants with other commonly available surfactants and usually deliver very specific niche properties in the formulation.

Recommended use levels for cleaning formulations containing DOWFAX surfactants typically vary between 0.1 and 5% on a weight basis. However, since

the majority of the DOWFAX surfactants are sold as a 45% active sodium salt in aqueous solution, the active ingredient concentration in a cleaning formulation is typically between 0.05 and 2.5%.

The following are typical examples of formulations containing DOWFAX surfactant:

Glass Cleaner Formulation

0.1%	Surfactant
3%	Isopropanol
3%	Glycol ether
93.9%	Water

Liquid Glass Bottle Washing Concentrate

2.4%	Gluconic acid (50%)
0.3%	DOWFAX Surfactant solution
0.08%	nonionic surfactant
50.22%	Water
47.0%	Sodium hydroxide (50%)

General Purpose Hard Surface Cleaner

90.5%	Deionized water
2.0%	Sodium silicate, anhydrous
2.0%	DOWFAX Surfactant solution
0.5%	Nonionic surfactant
5.0%	Glycol ether

Acid Based Industrial Cleaner

70.3%	Water
26.7%	Hydrochloric Acid
0.5%	Alcohol ethoxylate
2.5%	DOWFAX Surfactant solution

Industrial Degreaser

84%	Water
2%	EDTA chelating agent
1%	DOWFAX Surfactant solution
5%	Sodium citrate
5%	Glycol ether

3% Nonionic surfactant

Occupational Exposure Limit Values (IUCLID 1.8)

In keeping with the historical treatment of this class of substances as a category with similar hazards and risks, the occupational exposure limit of 5 mg/m3 for DOWFAX 2A1 anionic surfactant (CAS 119345-04-9) has been considered representative for the class. This is a Dow Industrial Hygiene Guide (TWA for 8-hour day). DOWFAX 2A1 anionic surfactant is also the Dow product with the highest sales volume of the class.

Source of Exposure (IUCLID 1.9)

Exposure during manufacturing: DOWFAX surfactant solutions are manufactured in closed systems where reactors and downstream equipment are hard-piped, to minimize losses to the environment and also exposure to employees.

DOWFAX surfactants are sold in drums, totes or in bulk.

Exposure during use: (Emulsion Polymerization):
DOWFAX 2A1 is typically used at levels between 0.5 % to 5 % based on monomers in the latex manufacturing process. The surfactant is fed either together with the monomers as an emulsion or separately as an aqueous feed to the reactor together with the monomer feed and the initiator feed. Polymerization occurs in the reactor over several hours. In a finishing step of the polymerization a redox shot is injected to the reactor to maximize monomer conversion or a stripping operation is made. During the stripping operation steam is injected to the latex and a monomer-water azeotrope is extracted. The azeotrope is further condensed and separated between monomer and water-surfactant phase. The water-surfactant stream is most often polluted by a small amount of latex and known as white water. The white water is most often reused in next production batches. Some white water is also generated during cleaning of reactors and feeding tanks. The white water is generally treated by aluminum sulfate to precipitate out the polymer. Aluminum sulfate tends to also precipitate out most of the DOWFAX 2A1 . The treated white water is then sent to the biox station. DOWFAX 2A1 is then degraded into a C4 carboxylate intermediate, which has extremely low toxicity to aquatic organisms. This intermediate is then further degraded to the point of mineralization.

Exposure during use: (Industrial Cleaning Applications):

DOWFAX 2A1 is typically used at levels between 0.05 % to 2 %, depending upon the severity of the cleaning application. The cleaning solution, as noted above, may be diluted prior to use due to the solubility of the DOWFAX. The cleaning solutions may also be recycled a number of times before the surfactant stream is sent either to an on-site water treatment area or discharged, upon dilution, to a municipal waste water treatment facility, where chemical and biological degradation occur.

Physical/Chemical Properties (IUCLID 2.1, 2.2, 2.4, 2.5 and 2.6.1)

As noted in the table, melting point, boiling point, and vapor pressure for the aqueous products were populated with the chemical-specific data generated using the EPI/WIN* [1999] model as developed by the EPA. The octanol/water partition coefficient was populated using the ACD/Log D program from ACD Labs; although those values should be viewed with caution because this measure of lipophilicity is estimated with difficulty with surface-active molecules such as the ADPODS. Water solubility was defined based on product dilutions that range from 10% to 50% aqueous. Additional physical/chemical property data were generated by actual measurements using the dry hydrotrope powder for the C6 substance as well as for the aqueous C16 product.

Sufficient data are available and no further testing is required for physical/chemical properties. The ADPOD Chemical/Physical Properties are summarized in the *Appendix A*. The octanol/water partition coefficients (Kow) for the ADPODS's cannot be determined by OECD procedures because of the surface-active properties of the materials. The OECD 107 method (Partition Coefficient; n-octanol/water) states that, "The method applies only to pure, water soluble substances which do not dissociate or associate and which are not surface active." The OECD 117 method (Partition coefficient, n-octanol/water, HPLC method) also states that, "the method is not applicable to strong acids and bases, metal complexes, substances which react with the eluent, and surface active agents."

Photodegradation (IUCLID 3.1.1)

Due to extremely low vapor pressures, these substances are not likely to be found in air. Thus, there seems to be no basis for estimating the photodegradation potential of these materials.

Hydrolysis (IUCLID 3.1.2)

These substances have no hydrolyzable functional groups so hydrolysis is not expected. There was no significant hydrolysis as a function of pH (Brekelmans, 1998 and Gladdines, 1995a). Thus, there seems to be no basis for conducting further tests in this area.

Fugacity (Environmental Transport) (IUCLID 3.3.1)

Mobility in soil is normally expected to be a function of the length of the sidechain, with short chain more mobile than long-chain. That is borne out in two soil adsorption/desorption studies--C16/ CAS 65143-89-7, Gladdines, 1995b and C6/CAS 147732-60-3, Willems, 1998. The adsorption/desorption study with the C16 (Dowfax 8390) shows it to be relatively immobile in soil; it has high soil adsorption rates but low desorption rates . In the case of the C6 ADPODS, the Willems study shows that it is highly mobile in soil due to low adsorption. In another study of the relative behaviors of three of these ADPODS and sodium dodecylbenzenesulfonate for use in subsurface remediation (Rouse, etal, 1993) more consistency of behavior within the series was observed. This third study showed that the three tested products (Dowfax 3B2, XDS-8174.00, and Dowfax 8390) all behaved similarly in Canadian River alluvium under laboratory conditions. They were all less susceptible to sorption than either the nonionic surfactants or monosulfonate surfactant tested. The Rouse, 1993, study also shows that the three Dowfax products behaved similarly with regard to precipitation and solubilization potential under the tested remediation conditions.

ADPODS would be expected to reside in soil and/or water compartments where they may be expected to undergo slow biodegradation including mineralization under aerobic environmental conditions. DOWFAX 8390-D was hydrolytically stable at various pH's in the absence of biomass (Gladdines, 1995a). These materials are not likely to be found in air because they have such low vapor pressures.

Test Plan: While these compounds would be expected to reside in soil and water, not air, due to their physical properties, the transport percentages between the environmental compartments has not been estimated. We propose to conduct Level I Fugacity modeling on the compounds at the boundary of the category, the C6 Linear, Na Salt (147732-60—3) and the C16 Linear, Na Salt (65143-89-7).

Biodegradation (IUCLID 3.5)

Biodegradation data have been generated for 5 of the 7 group substances. The two having no data were the acid forms of tested (sodium salt) materials. Thus, the data range can be considered complete.

Several of the ADPODS's are biodegradable according to SDA (Soap and Detergent Association) Semi-Continuous Activated Sludge (SCAS) confirming tests for anionic surfactants. (Though substantial biodegradation was observed, the C6 and branched C12 (DOWFAX 2A1) surfactants did not meet the SDA criteria of >90% biodegradation based on methylene blue active substance assay to be classified as "biodegradable".) The Dry Hydrotrope Powder (C6) gave variable results. It showed no biodegradation after 28 days in the CO2 Evolution Test for ready biodegradability (Desmares-Koopmans, 1998a); however, neither did it show any inhibitory effect on that sludge (Desmares-Koopmans, 1998 b). In the SDA test it produced a mean of 73% MBAS removal during 21 days in the SCAS test.

Although not all members of the group have been tested, several of the ADPODS's are considered inherently biodegradable with >20% biodegraded based on an OECD test for inherent biodegradability (CAS 119345-04-9, Gonsior, 1998) and data from other related kinds of tests.

In Rhinehart and Bailey, 1978, additional information about aquatic behavior of these materials was presented. When C^{14}-radiolabeled DOWFAX 2A1 anionic surfactant was used to determine adsorption in sludge, the data showed that all of the test material remained in solution--thus, no adsorption occurred thus eliminating adsorption as a confounder in biodegradation findings.

Acute Aquatic Toxicity (IUCLID 4.1, 4.2, 4.3)

For fish toxicity parameters, sufficient data currently exist to adequately populate [or interpolate] the remaining individual chemical data cells. For acute daphnia and acute fish toxicity assessment, only the C10 acid form and the C12 branched acid forms remain untested--while their sodium salt forms were tested.

Linear regression analysis of acute toxicity data for freshwater fish exposed to Dow anionic surfactants (alkyl chain lengths of 6 to 16 total carbons) suggests

that acute freshwater fish LC50 values will generally decline with increasing total number of carbons in the surfactant alkyl chains (see Figure 1). The data represented in Figure 1 were collected using juvenile rainbow trout and fathead minnows.

While the ADPODS chemicals vary in their toxicity to fish (96-hr LC50's in the range of 0.42 to 13 mg/l), when they are allowed to biodegrade in sludge, the aquatic toxicity of the biodegradation products is substantially reduced (96-hr LC50's in the range of >7 to >30 mg/l) (Rhinehart and Bailey, 1978). These authors reported that 'the metabolites are believed to be end-chain carboxylates which retain methylene blue activity (surfactant activity) but which are less toxic to aquatic organisms'. The same reduction in toxicity between the parent surfactant and the biodegradation products was seen in the chronic toxicity tests conducted on daphnia (as reported in the next section--Henry, 2001 and Bogers, 1996). Similar properties on the attenuation of fish toxicity for biodegradation products have been observed in the alkylbenzene sulfonate series (Kimerle and Swisher, 1977).

Test Plan. Because of some inconsistency in daphnia data, and in order to have a complete data set for all members of the category, we propose acute daphnia tests on the C10 and C12 acid members of the group. This should not only complete the data set but also help determine if there are any 'outlying' data in the collection.

Chronic Aquatic Toxicity (IUCLID 4.5.1, 4.5.2)

The chronic toxicity of DOWFAX XDS-8174.00 surfactant was assessed in a flow-through embryo-larval test with the fathead minnow. The NOEC was 25 µg/l and the Maximum Acceptable Toxicant Concentration (MATC), based on larval survival, was 30 µg/l (Dill, etal, 1990).

In an OECD 211 study to evaluate the chronic effects of Daphnia magna exposed to the degradation products of DOWFAX 8390, it was shown that the surfactant is biodegraded during the wastewater treatment process (degradation of aliphatic side-chain to carboxylate). There was no reduction in survival, reproductive capacity, nor growth of Daphnia magna in up to 100% treated effluent from activated sludge amended with DOWFAX 8390 (initial concentration of 20 mg/l) aged for 7 days (Henry, 2001). In contrast, in an OECD 202 study on DOWFAX 8390 parent material, the overall NOEC for

daphnia reproduction was 0.7 mg DOWFAX 8390-D/l (based on measured material at 72 hrs) (Bogers, 1996).

These data collectively indicate that dose levels of DOWFAX 8390 (a 'linear' C16 sodium salt material) acutely toxic to Daphnia magna may be toxicologically deactivated after aging in the presence of activated sludge for a period of 7 days. This conclusion is based on the fact that the initial test dose level of 20 mg/l is ~50% above the 48-hr EC50 value of ~14 mg/l with Daphnia magna and the resulting 7-day sludge effluent was not acutely or chronically toxic following a 21-d life-cycle study with daphnia.

Acute Mammalian Toxicity (IUCLID 5.1.1, 5.1.3, 5.2.1, 5.2.2)

For acute mammalian toxicity, adequate data currently exist to populate the individual chemical data cells. These data are fully summarized in the Robust Summaries in IUCLID.

Acute toxicity data have been collected over decades for these materials. The data collected have been consistent over time. The most recent studies were conducted according to OECD guidelines, for the most part. The ADPODS's are low in acute toxicity but topical irritancy varies with form and concentration. Exposure via inhalation is unlikely due to the extremely low vapor pressures of these substances. Use dilutions of the substances are not skin sensitizers; however, highly concentrated solutions have produced positive sensitization responses in two of the various guinea pig studies.

Repeated Dose Toxicity (IUCLID 5.4)

There are several studies in which ADPODS category members have been tested for repeated dose toxicity. These studies indicate the ADPODS's to be low in systemic toxicity upon repeated dosing. The liver, and possibly kidney, are the systemic primary target organs while the gastrointestinal tract also showed effects due to irritation . The NOAEL for repeated dose toxicity for the various members of this ADPODS category is consistent, and within a relatively narrow range from 50 to 500 mg/kg/day, based on a composite evaluation of all the repeated dose toxicity studies, including studies ranging in duration from one month up to two years. These repeated dose toxicity studies have also reported a similar and common profile of target organs. Thus, the results of the collection of

sub-chronic and chronic studies conducted on these substances are consistent and can be regarded as offering a true picture of repeated dose toxicity.

Test Plan. The data collection for the category is deemed to be complete; however, in conjunction with the plan to conduct an OECD 422 study of the C6 and C16 products, additional data will be generated.

Genetic Toxicity '*in vitro*' (IUCLID 5.5)

For mutagenicity, currently available *in vitro* data from tests for gene mutations as well as from tests for chromosomal damage exist for the chemicals that define the lower and upper boundaries of the Category [C6, C16 Alkyl chain lengths].

These studies are all negative for genotoxicity--with and without an external metabolic activation system, except for one study in which there was a dose-related positive response which at the time was attributed to the sample having 210 ppm peroxide as an unwanted constituent. Peroxide is no longer used in the ADPODS process; thus, the potential for peroxides to be present in commercially available products no longer exists. Based on studies conducted on the C6 and C16 members of the group, including more recent studies conducted using guideline methodology, it can be concluded that the ADPODS materials are not considered to be mutagenic.

As *in vitro* genotoxicity data have been generated on the C6 and C16 products, the entire category is bracketed, and no additional *in vitro* genotoxicity data are deemed necessary to allow interpolation from the currently existing data.

Genetic Toxicity '*in vivo*' (IUCLID 5.6)

With regard to *in vivo* genotoxicity tests, there was no evidence of genotoxicity based on a cytogenetic analysis of rat bone marrow cells from a study with the the C16 substance that was a supplement to the 90-day subchronic study**.** In this test, groups of 5 male and 5 female Sprague-Dawley rats/dose were fed diets containing DOWFAX XD 8390 (CAS 65143-89-7) for 90 days in doses of 0, 50, 100 or 600 mg/kg/day. Cytogenetic analysis of 50 metaphase spreads from each of the males and nearly 50 from each of the females revealed findings judged to be within the control range (Johnston, etal, 1977).

Due to the negative in vitro test results and the lack of genotoxicity in the *in vivo* study of the C16 product, no additional *in vivo* testing is proposed.

Carcinogenicity (IUCLID 5.8)

Chronic feeding studies have been conducted in two species, namely the rat and the dog with DOWFAX 2A1 (CAS 119345-04-9). These studies were conducted in 1963 according to standard procedures at the time. While no carcinogenic response was observed in either the dog or the rat, the study in rats is considered more representative of the conventional lifetime exposure methodology currently used for evaluation of carcinogenic potential of a substance. Groups of 50 rats/sex/dose were fed diets containing 0, 0.03, 0.1, 0.3 and 1.0 % of the active ingredient of Benax (DOWFAX) 2A1 (0, 15, 50, 150 and 500 mg/kg/day) for 2 years. Interim sacrifices of approximately 10 rats/sex/dose were conducted at 12 and 18 months, and the remaining groups were maintained for the duration of the two year dosing period. Other than body weight differences, there were no adverse effects attributed to treatment in this study. Even at the high dose level of 500 mg/kg/day there was no tumorigenic response (Beatty, 1963b).

It is believed that no additional carcinogenicity testing is necessary.

Toxicity to Reproduction (IUCLID 5.8)

There is one previous study of the reproductive effects of an ADPODS category member--a Chernoff test. In this study, DOWFAX C6L surfactant (CAS 147732-60-3) was fed by gavage to groups of pregnant Fischer 344 rats from day 6 of gestation through day 3 post-partum. The doses were 0, 300 and 1000 mg/kg/day. Both doses produced significant depression of maternal weight gain. Evaluation of the litters for mean litter size, neonatal growth and survival through the first 3 days post-partum did not reveal any significant adverse effects at either dose (Hanley, etal, 1985).

Also, data developed during the conduct of the multiple repeated dose toxicity tests in rats and dogs lend support to the lack of an effect on reproduction. In those repeated dose tests, with dosing durations from one month up to two years, various reproductive and endocrine organs were weighed and/or examined grossly and microscopically. In all instances, there were **no adverse**

effects in any of these organs. Available data support the position that this category of substances has not elicited reproductive toxicity.

Reproductive and Endocrine Examinations in Subchronic and Chronic Studies

Chemical	Study	Reproductive Examination
C6 Linear, Na salt	28-Day Rat Oral Gavage	Testes/adrenals weighed and examined
	10-Day Rat Oral Gavage (dose-setting for Chernoff)	Thymus weighed and complete gross pathologic examination
C10 Linear, Na salt	92-Day Rat Diet (data from non-commercial structurally-related material)	Testes weighed. Testes, coagulating gland, seminal vesicles, adrenals, thyroids, parthyroids, pituitaries, thymus, ovaries and uterus all examined histologically
	95-Day Dog Diet (data from non-commercial structurally-related material)	Testes weighed. Testes, pituitaries, adrenals, ovaries and uterus examined histologically
C12 Branched, Na salt	90-Day Rat Diet	Testes weighed. Testes and adrenals examined histologically
	95-Day Dog Diet	Testes weighed. Testes, adrenals, thyroids, and pituitaries examined histologically
	2-Year Dog Diet	Testes weighed. Testes, pituitaries, thyroids, adrenals, thymus, ovaries, and uterus examined histologically
	2-Year Rat Diet	Testes weighed. Testes, adrenals and prostates examined histologically
C16 Linear Na salt	90-Day Rat Diet	Testes weighed. Testes, adrenals, epididymides, thyroids, parthyroids, pituitaries, prostates, mammary tissue (F), ovaries, uterus and thymus examined histologically
	28-Day Rat Diet	Testes and adrenals weighed. Adrenals examined histologically
	90-Day Dog Diet	Testes weighed. Testes, adrenals, epididymides, parthyroids, pituitaries, prostates, mammary tissue (F), ovaries and thymus examined histologically

Test Plan. To supplement the data currently available on this endpoint, this test plan proposes to conduct the combined repeat dose / reproductive / developmental toxicity test [OECD Test Guideline #422] on each of the two chemicals that have been added to the submission in order to strengthen the HPV category [C6, C16 Alkyl chain lengths]. The resultant data from these studies will be used for representation of the entire ADPODS group, encompassing the remaining chemical data cells within the category

Appendix A outlines the available HPV-specific data and projected Test Plan for Generation/Summarization of the relevant data for the ADPODS Category as requested under the HPV Challenge program. *Appendix B* outlines how the HPV Endpoints will be met for each HPV compound through the use of data across the ADPODS Category.

It is anticipated that the additional data generated during the conduct of the studies outlined above will further validate the Category approach used for the ADPODS chemicals included in this Category.

IV. Conclusions

Evaluation of this tabulation leads to the conclusions that [1] a substantial amount of data currently exists to adequately represent the toxicological and ecological profile of major portions of this category, [2] there is a concurrence and similarity among the existing data for the various HPV/SIDS endpoints, supporting a single, continuous category, [3] extrapolation from available data from previously conducted studies can be used to adequately represent most of the HPV/SIDS endpoints for individual members of the category, and [4] to supplement the currently available data, the following tests are proposed to be conducted:

OECD Endpoint	Test	Category Representative Member Substance to be Tested
Model	Fugacity (Environmental Transport)	C6 and C16 Linear Salt forms of ADPODS (CAS: 147732-60-3 and 65143-89-7)
202	Acute Daphnia	C10 and C12 Acid forms of ADPODS (CAS: 70191-75-2 and 119345-03-8)
422	Combined Mammalian Repeat Dose/Repro/Develop. Screen	C6 and C16 ADPODS (CAS: 147732-60-3 and 65143-89-7)

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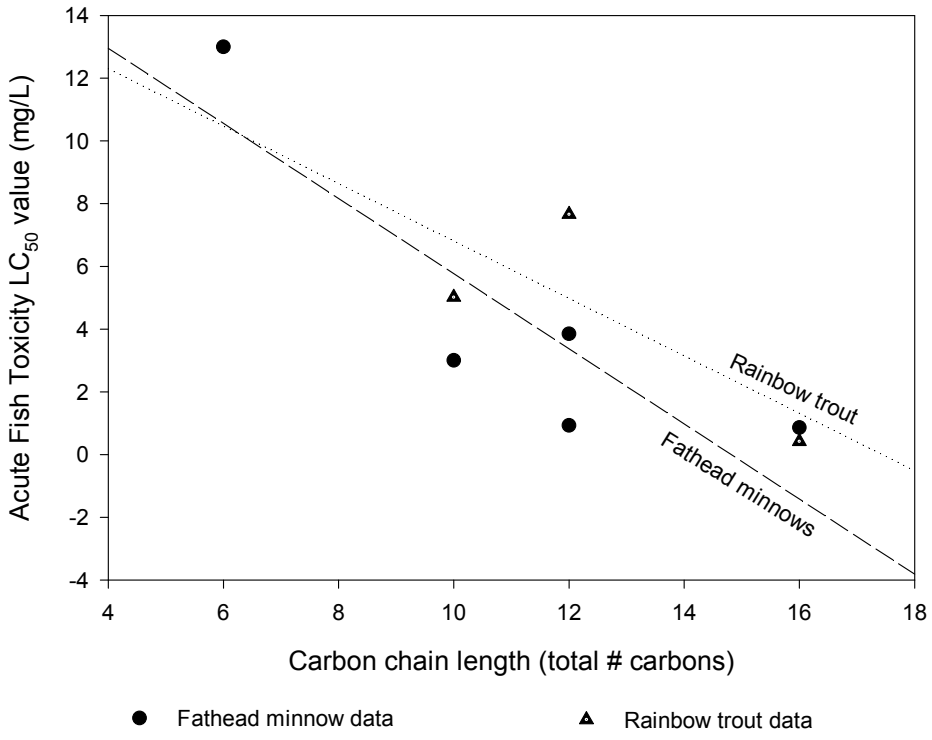
Figure 1: Acute fish toxicity (96-hr LC50 values) versus carbon chain length for Dow ADPODS Surfactants



The Dow Chemical Company December 2002			ADPODS DATA SUMMARY APPENDIX A					
		1	2	3	4	5	6	7
	Description	C6 Linear, Na Salt	C10 Linear, Acid	C10 Linear, Na Salt	C12 Linear, Na Salt	C12 Branched, Acid	C12 Branched, Na Salt	C16 Linear, Na Salt
	Description	DOWFAX* C6L	DOWFAX* 3B0	DOWFAX* 3B2	XDS-8174.00	DOWFAX* 2A0	DOWFAX* 2A1	DOWFAX* 8390
	CAS #	147732-60-3	70191-75-2	36445-71-3	149119-20-0	119345-03-8	119345-04-9	65143-89-7
OECD	Tests/Studies:							
	Physical/Chemical Properties							
102	M.P.	dec >265 C [1]	290 C *	290 C *	300 C *	298 C *	298 C *	dec. 320 C [2]
103	B.P. (EPIWIN estimation)	610 C	660 C	660 C	680 C	660 C	660 C	None: (water boils off) [2]
104	V.P. (mm Hg)	1.66x10-2 [1]	5x10-19 *	5x10-19 *	6x10-20 *	4x10-19 *	4x10-19 *	8x10-22 *
107	Part. Coeff. (Log Pow)	0.6 [1]	2.7 #	2.7 #	3.8 #	3.3 #	3.3 #	Fat solubility: < 95x10-3 g/l [2]
105	Water Solubility (mg/L or description)	1:1 [1]	>100,000 **	>100,000 #	>100,000 #	>100,000 #	>100,000 #	>100,000 #
	Environmental Fate							
	Photodegradation	No data; Not present in air	No data; Not present in air	No data; Not present in air	No data; Not present in air	No data; Not present in air	No data; Not present in air	No data; Not present in air
111	Hydrolysis	No hydrolyzable functional groups	No hydrolyzable functional groups	No hydrolyzable functional groups	No hydrolyzable functional groups	No hydrolyzable functional groups	No hydrolyzable functional groups	No hydrolyzable functional groups
	Fugacity (Environmental Tranport)	Fugacity Level I Model Proposed	Category analogy	Category analogy	Category analogy	Category analogy	Category analogy	Fugacity Level I Model Proposed
302	Biodegradation	79% biodegradation in 7 days; Dry Hydrotrope Powder: 73% in 21 days	Biodegradable (SDA criteria) See salt form which was tested	Biodegradable (SDA criteria) 6 Tests: 77 to 98.7% biodegradation in 7 to 28 days (Dry Hydrotrope Powder not biodegradable in CO2 Evolution Test; but not inhibitory towards aerobic waste water bacteria.)	Biodegradable (SDA criteria) 99.6% biodegradation after 23 hours (linear product)	Inherently Biodegradable (OECD criteria) See salt form which was tested	Inherently Biodegradable (OECD criteria) 4 Tests: 21 to 51% biodegradation after 7 to 21 days	Biodegradable (SDA criteria) Inherently Biodegradable (OECD criteria) 5 Tests: 54 to >99% biodegradation after 7 to 28 days. MADS degraded to disulfodiphenyl oxide carboxylate--Mineralization to CO2 observed in surface soil and aquatic sediment. Little mineralization observed in activated sludge--no biodegradation under anaerobic conditions.
	Aquatic Organisms							
203	Acute Fish (LC50)	FHM: 13 mg/l in 96 hrs; Carp: 6.8 mg/l in 96 hrs (Dry Hydrotrope Powder)	Salt form tested	FHM: ~3 to 3.66 mg/l; Bluegill: 4.99 mg/l; RBT: 5.02 mg/l all in 96 hrs	FHM: 0.93 mg/l in 96 hrs	Salt form tested	RBT: 7.66 mg/l; FHM: 3.85 to >30 for biodegradation products; Bluegill: 6.81 mg/l all in 96 hrs	RBT: ~0.42 to 0.7 to >20 mg/l (for biodegradation products); FHM: 0.86 and 1.03 mg/l (2 lots)
	Chronic fish	Category analogy	Category analogy	Category analogy	32-Day NOEC 25 microg/l and MATC 30 microg/l	Category analogy	Category analogy	Category analogy
202	Acute Daphnia (LC50)	47 mg/l in 48 hrs; EC50: 11.8 mg/l in 48 hrs (Dry Hydrotrope Powder)	Salt form tested **202 Test Proposed on acid**	~1 to 1.51 mg/l in 48 hrs	4.6 mg/l in 48 hrs	Salt form tested **202 Test Proposed on acid**	0.58 to 5.8 mg/l all in 48 hrs (Toxicity reduced 100-fold after exposure to activated sludge)	13.9 to 14.1 to >20 mg/l (for biodegradation products)

	Chronic Daphnia	Category analogy	Category analogy	Category analogy	Category analogy	Category analogy	Category analogy	21-Day: No toxicity in up to 100% activated sludge amended with Dowfax 8390---------- ---------- -21-Day Reprod.: NOEC = 1 mg/l (nominal); NOEC: 0.7 mg/l (measured)
201	Acute Algae	NOEC: 10.0 mg/l (growth inhibition) and 22 mg/l (growth rate reduction) (Dry Hydrotrope Powder)	Category analogy	Category analogy	NOEC: 297.5 mg/l in 120 hrs	Category analogy	Category analogy	NOEC: 10 mg/l in 72 hrs
	Acute Mammalian Toxicity							
401	Acute Oral (LD50/Rat)	>2000 or >5000 mg/kg (3 studies)	1000 - 2000 or 3011 mg/kg (2 studies)	6 studies: range 1000 - 2000 to 3562 mg/kg	>2000 mg/kg	>500 and ~1000 - 2000 mg/kg (2 studies)	3 studies: 1000 - 2000 mg/kg; 1976; >2000 mg/kg	>5000 mg/kg (2 '401' studies)
	Note: Skin and eye irritancy vary by product concentration and form (acid vs. sodium salt)--See Individual Data Appendix Table 1 and Robust Summaries							
	Repeated Dose Toxicity							
		28-Day Rat Oral Gavage: NOAEL 50 ma/kg/day---------- ---------- 10-Day Rat Oral Gavage: NOAEL 367 mg/kg/day	Category analogy	92-Day Rat Diet: NOAEL 500 mg/kg/day---------- ---------- 95-Day Dog Diet: NOAEL 163-177 mg/kg/day---------- ---------- (data for non-commercial Benax 3B1 which is closely related structurally to Dowfax 3B2.)	Category analogy	Category analogy	90-Day Rat Diet: NOAEL 0.3% in feed (~150 mg/kg/day)---------- ---------- 95-Day Dog Diet; NOAEL 131 mg/kg/day-- ---------- 2-Year Dog Diet: NOAEL 128 mg/kg/day-- ---------- 2-Year Rat Diet: NOAEL 150 mg/kg/day	90-Day Rat Diet: NOAEL 100 mg/kg/day---------- ---------- -28-Day Rat Diet: NOAEL 250 mg/kg/day---------- ---------- 90-Day Dog Diet: NOAEL 200 mg/kg/day
	Genotoxicity							
	In Vitro Genotoxicity							
471	Ames	Negative (2 studies--one of Dry Hydrotrope Powder)	Category analogy	Category analogy	Category analogy	Category analogy	Category analogy	Negative
	Mammalian Gene Mutation	Category analolgy	Category analogy	Category analogy	Category analogy	Category analogy	Category analogy	Negative--CHO/hgprt
	Chromosomal Aberration	2 Negative--Rat lymphocytes---------- ---------- Positive--human lymphocytes (attributed to 210 ppm peroxide in sample)	Category analogy	Category analogy	Category analogy	Category analogy	Category analogy	Negative--human lymphocytes---------- ---------- Negative--rat lymphocytes
-474	In Vivo Chromosomal Aberration	Category analolgy	Category analogy	Category analogy	Category analogy	Category analogy	Category analogy	Negative--rat bone marrow cytogenetics
	Reproduction							

422	Combined Repeat Dose/Repro/ Develop. Screen	Chernoff Test: NOAEL: <300 mg/kg/day for maternal toxicity-- NOAEL: >1000 mg/kg/day for developmental **422 Proposed**	Category analogy	Category analogy	Category analogy	Category analogy	Category analogy	**422 Proposed**
	(Additional data related to reproduction--and no adverse effects observed)	28-Day Rat Oral Gavage: testes and adrenals weighed and examined histologically. ---------- 10-Day Rat Oral Gavage (dose-seting for Chernoff): thymus weighed and complete gross pathologic exam performed.	Category analogy	92-Day Rat Diet: Testes weighed. Testes, coagulating gland, seminal vesicles, adrenals, thyroids, parathyroids, pituitaries, thymus, ovaries, and uterus examined histologically.---------- ----------95-Day Dog Diet: Testes weighed. Testes, pituitaries, adrenals, ovaries and uterus examined histologically. (data for non-commercial Benax 3B1, a structurally similar material)	Category analogy	Category analogy	90-Day Rat Diet: Testes weighed. Testes and adrenals examined histologically.---------- ---------- 95-Day Dog Diet: Testes weighed. Testes, adrenals, thyroids, and pituitaries examined histologically. ---------- ---------- 2-Year Dog Diet: Testes weighed. Testes, pituitaries, thyroids, adrenals, thymus, ovaries, and uterus examined histologically.---------- ---------- 2-Year Rat Diet: Testes weighed. Testes, adrenals and prostates examined histologically.	90-Day Rat Diet: Testes weighed. Testes , adrenals, epididymides, thyroids, parathyroids, pituitaries, prostates, mammary tissue (F), ovaries, uterus and thymus examined histologically.---------- ---------- 28-Day Rat Diet: Testes and adrenals weighed. Adrenals examined histologically.---------- ---------- -90-Day Dog Diet: Testes weighed. Testes, adrenals, epididymides, parathyroids, pituitaries, prostates, mammary tissue (F), ovaries and thymus examined histologically.
	*EPIWIN estimation							
	#ACD/Log D estimation							
	**Solubility based on formulation							
	MADS = Monoalkylated disulfonated component							
	FHM = Fathead minnow							
	RBT = Rainbow trout							
	[1] Tests conducted on Dowfax* Dry Hydrotrope Powder							
	[2] Tests conducted on Dowfax* XD 8390							

ADPODS CATEGORY ASSESSMENT APPENDIX B

		1	2	3	4	5	6	7
	Description	C6 Linear, Na Salt	C10 Linear, Acid	C10 Linear, Na Salt	C12 Linear, Na Salt	C12 Branched, Acid	C12 Branched, Na Salt	C16 Linear, Na Salt
	Product Name (main)	DOWFAX* C6L	Dowfax 3B0	DOWFAX* 3B2	XDS-8174.00	DOWFAX* 2A0	DOWFAX* 2A1	DOWFAX* 8390
	CAS #	147732-60-3	70191-75-2	36445-71-3	149119-20-0	119345-03-8	119345-04-9	65143-89-7
OECD	Tests/Studies:							
	Physical/Chemical Properties							
102	M.P.	DA	CQ	CQ	CQ	CQ	CQ	CQ
103	B.P. (EPIWIN estimation)	CQ	CQ	CQ	CQ	CQ	CQ	CQ
104	V.P. (EPIWIN estimation)							
107	Part. Coeff.	DA	CQ	CQ	CQ	CQ	CQ	CQ
105	Water Solubility (based on product) mg/l	DA	CQ	CQ	CQ	CQ	CQ	CQ
	Environmental Fate							
	Photodegradation	NR	NR	NR	NR	NR	NR	NR
111	Hydrolysis	NR	NR	NR	NR	NR	NR	NR
	Fugacity	DP	AN	AN	AN	AN	AN	DP
302	Biodegradation	DA	AN	DA	DA	AN	DA	DA
	Aquatic Organisms							
203	Acute Fish (LC50)	DA	AN	DA	DA	AN	DA	DA
	Chronic fish	AN	AN	AN	DA	AN	AN	AN
202	Acute Daphnia (LC50)	DA	**DP**	DA	DA	**DP**	DA	DA
	Chronic Daphnia	AN	AN	AN	AN	AN	AN	DA
201	Acute Algae	DA	AN	AN	DA	AN	AN	DA
	Acute Mammalian Toxicity							
401	Acute Oral (LD50/Rat)	DA	DA	DA	DA	DA	DA	DA
	Repeated Dose Toxicity							
		DA	AN	DA	AN	AN	DA	DA
	Genotoxicity							

	In Vitro Genotoxicity									
471	Ames	DA	AN	AN	AN	AN	AN	DA		
	Mammalian Gene Mutation	AN	AN	AN	AN	AN	AN	DA		
	Chromosomal Aberration	DA	AN	AN	AN	AN	AN	DA		
474	In Vivo Chromosomal Aberration	AN	AN	AN	AN	AN	AN	DA		
	Reproduction									
422	Combined Repeat Dose/Repro/ Develop. Screen	DA, **DP**	AN	AN	AN	AN	AN	**DP**		
	(Additional data related to reproduction--and no adverse effects observed)	DA, **DP**	AN	DA	AN	AN	DA	DA		
	DA=Data acceptable									
	CQ=Calculated/QSAR									
	AN=Category analogy/data not required									
	DP=Data collection proposed									
	NR=Not required									